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APPLICATION NO. FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. 09/036,053 03/06/98 **EPPSTEIN** J 19141.0001 **EXAMINER** QM12/1015 D ANDREW FLOAM BOCKELMAN, M NEEDLE & ROSENBERG PAPER NUMBER **ART UNIT** SUITE 1200 THE CANDLER BUILDING 127 PEACHTREE STREET N E 3763 ATLANTA GA 30303-1811 DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

10/15/99

	Application No.	Applicant(s)	licant(s)		
Office Action Summany	09/036,053	Eppstein			
Office Action Summary	Examiner		Group Art Unit		
	Bockelma	<u>^</u>	3763		
-The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address-					
Period for Reply					
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIREMONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.					
 Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication. Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). 					
Status					
□ Responsive to communication(s) filed on					
☐ This action is FINAL.					
☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 1 1; 453 O.G. 213.					
Disposition of Claims					
\Box Claim(s) $1-21, 29, 32-45$		is/are pending in the application.		lication.	
	pove claim(s) 32 - 43 is/ar				
			is/are allowed.		
Defaim(s) 1-15, 17-18, 21			is/are rejected.		
□ Claim(s) □ Claim(s) 1-15, 17-18, 21 □ Claim(s) 16, 19-20 and 44			is/are objected to.		
☐ Claim(s)			ject to restriction o	or election	
Application Papers		require	ment.		
☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.					
☐ The proposed drawing correction, filed on is ☐ approved ☐ disapproved.					
☐ The drawing(s) filed on is/are objected to by the Examiner.					
☐ The specification is objected to by the Examiner.					
☐ The oath or declaration is objected to by the Examiner.					
Priority under 35 U.S.C. § 119 (a)-(d)					
 □ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d). □ All □ Some* □ None of the CERTIFIED copies of the priority documents have been □ received. 					
received in Application No. (Series Code/Serial Number)					
☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).					
*Certified copies not received:					
Attachment(s)	4				
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s	i)				
☑ Notice of Reference(s) Cited, PTO-892	☐ Notice of Informal Patent Application, PTO-152				
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948	0	ther			
Office Action Summary					

U. S. Patent and Trademark Office PTO-326 (Rev. 9-97)

Part of Paper No.

Art Unit: 3762

DETAILED ACTION

Election/Restriction

1. Claims 32-43 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected invention III. Election was made without traverse in Paper No.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.
- 3. Claims 1-3, 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Gerstel et al 3,964,482.

Gerstel teaches a device that microporates the skin using probes 12, flux enhancers 48-64 and diuretics (column 14 line 9) as one of the many drugs.

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4. Claims 1, 3, 8-9, 13, 17-18, 21, 29, 45 are rejected under 35 U.S.C. 102(e) as being anticipated by Johnson et al USPN 5,947,921.

Johnson teaches the mixing of electroporation, ultrasound and flux enhancers to both deliver drugs as well as extract analytes which can also include suction (column 9 line 1-11) as well as inflammatory mediators in the form of corticosteroids.

5. Claims 1 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Ammonia Amplifies Nicotine, Study Confirms by John Schwartz...

The examiner considers the alveoli I the lungs which absorbs both ammonia and Nicotine to be micropores.

Claim Rejections - 35 USC § 103

- 6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 7. Claims 2, 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. USPN 5,947,921 in view of Gerstel USPN 3,964,482 and Lee et al USPN 5,250,023.

 Applicant differs from Johnson et al. in reciting a probe that is heated to carry the flux enhancer.

 Gerstel shows that it was known to deliver flux enhancers as carried by microprobes 12 to help

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penetrate the stratum corneum. To have provided the Johnson et al device with such structure for similar reasons would have been obvious. Without specifying a datum point, all probes are considered heated.

8. Claims 4-6, 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al USPN 5,947,923 in view of Bettinger USPN 5,427,585.

Applicant differs from Johnson in providing a heating element to heat the treatment site.

Bettinger shows such a device to pretreat the skin for enhanced delivery. To have provided

Johnson with the heating device of Bettinger for similar reasons would have been obvious. It is

noted that the ethanol that Johnson et al uses is known to vaporize at room temperature. The

added heat from resistance heating would cause even faster vaporization.

Allowable Subject Matter

9. Claims 16, 19-20 and 44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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Any inquiry concerning this communication or earlier communications from the examiner 10. should be directed to Mark Bockelman whose telephone number is (703) 308-2112. If attempts

to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wynn Wood-

Coggins, can be reached at (703) 308-1344. The main fax phone number for this Group is (703)

305-3590. Any inquiry of a general nature or relating to the status of this application or

proceeding should be directed to the Group receptionist whose telephone number is (703) 308-

0858.

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October 12, 1999